

1 UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY

3 _____ : CIVIL ACTION NUMBER:
4 : 19-md-02875
5 IN RE: VALSARTAN PRODUCTS :
6 LIABILITY LITIGATION :
7 : DEPOSITION DESIGNATION
8 : HEARING VIA TEAMS
9 _____

10 Mitchell H. Cohen Building & U.S. Courthouse
11 4th & Cooper Streets
12 Camden, New Jersey 08101
13 September 30, 2024
14 Commencing at 10:01 a.m.

15 **B E F O R E:** THOMAS I. VANASKIE (RET.)
16 SPECIAL MASTER

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Proceedings recorded by mechanical stenography; transcript
produced by computer-aided transcription.

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1 (PROCEEDINGS held via Teams Conference before Special
2 Master Thomas I. Vanaskie at 10:01 a.m.)

3 SPECIAL MASTER VANASKIE: All right. We can go on the
4 record now.

5 We're going to be going over the designations --
6 deposition designations for several ZHP witnesses this morning.
7 We're going to go to 11:45 and then break for lunch and resume
8 about 1:00, so just to give you a heads-up on the schedule.

9 I thought we would start with -- and correct me
10 pronunciation, but Qiangming Li would be the first witness that
11 I would address.

12 And, Nina, I saw you smile when I pronounced that
13 name.

14 How do you pronounce it?

15 MS. ROSE: It's Qiangming Li.

16 SPECIAL MASTER VANASKIE: Qiangming Li, okay.

17 MS. ROSE: That one took me a while too.

18 (Laughter.)

19 SPECIAL MASTER VANASKIE: Phonetically they didn't do
20 it justice here.

21 All right. So --

22 MR. NIGH: And, Your Honor, while they're pulling that
23 up, if I can just briefly say something on the Torrent
24 witnesses.

25 We're going to be withdrawing -- in light of the

1 testimony that's already come in for Dawn Chitty and Jaiswal,
2 we're going to withdraw our designations on the
3 Jocelyn Rivera --

4 SPECIAL MASTER VANASKIE: Wonderful.

5 MR. NIGH: -- so you don't need to handle that one.

6 SPECIAL MASTER VANASKIE: All right. Yes.

7 MR. NIGH: Thank you.

8 SPECIAL MASTER VANASKIE: So that saves us time.

9 Thanks.

10 MR. NIGH: Sure.

11 SPECIAL MASTER VANASKIE: And I take it you informed
12 Ms. Lockard already?

13 MR. NIGH: Jacob and -- I think he's here -- I have
14 not yet, but I'm informing him now.

15 MR. RAE: This is Jacob Rae for Torrent. I had not
16 been informed of that, but I'm informed now. And obviously, we
17 are pleased with that news, and there's nothing -- no issue
18 with it from our perspective.

19 SPECIAL MASTER VANASKIE: All right. Super.

20 All right. Then let's begin now with the ZHP
21 witnesses and Qiangming Li, and the first excerpt I have is at
22 page 81, line 23 and 24 were the designation. And I guess it
23 starts with the question at lines 18 to 20.

24 Is that correct, Adam?

25 MR. SLATER: I think so, and you might even want to

1 look at the question and answer just before that starting at
2 line 10, just to see what line 18 was responding to, just to
3 get the full context.

4 SPECIAL MASTER VANASKIE: Okay. All right. So at
5 line 10, the question reads: How could ZHP control the
6 presence of NDMA in valsartan prior to June of 2018 if ZHP had
7 not detected NDMA in its valsartan?

8 And then the answer was: It was because we did not
9 have any knowledge of the existence or presence of NDMA prior
10 to that time that we did not control the presence of NDMA.

11 So that's what preceded the question that begins on
12 line 18, which is: And that's why it's important to conduct a
13 proper risk assessment prior to the manufacture of your
14 valsartan API, right?

15 That's the question. And you want the answer to stop
16 at line 24. So it would read: Judging from this sentence, I
17 agree it is important?

18 MR. SLATER: Yes, correct.

19 SPECIAL MASTER VANASKIE: And, Nina, you want the
20 answer to continue?

21 MS. ROSE: Yes, Your Honor. The plaintiffs'
22 designation cuts off just to include the first sentence of the
23 answer. The answer goes on from there. It's consistent with
24 the answer above and directly responsive to the question.

25 Also there's an issue -- they're only designating

1 "judging from this sentence," but there's no -- from what I can
2 see, I don't see what sentence is designated that he's
3 referring to. So it's confusing to have an answer that says,
4 "judging from this sentence."

5 Adam, please correct me if I'm wrong, if there's a
6 sentence that was designated.

7 MR. SLATER: I mean, if you want me to go back through
8 the rest of the designations and walk through the entire
9 foundation for this line of questioning. This is what your
10 client through into the answer to answer this. So I mean, if
11 we want to go back -- I don't have the full designations in
12 front of me, but we can go back and walk through it.

13 I didn't know that was the objection. I thought the
14 objection was the answer is not complete. Now I didn't -- we
15 can look at it if you'd like, you just have to show me, because
16 I didn't have that in front of me because I didn't know that
17 was the issue that you were raising.

18 MS. ROSE: Sure. I'm just noticing it right now.
19 Obviously, the objection is that the whole answer needs to be
20 included consistent with the Special Master's rulings thus far.

21 It's directly responsive. But as I was just reading
22 this and looking at the one part of the answer that you
23 designated, it refers to "judging from this sentence, I agree
24 it's important" --

25 MR. SLATER: I think he's talking about the question

1 he was asked. I think that's what he's talking about. I don't
2 think he's speaking to some specific sentence somewhere. I
3 think he's talking about the sentence that was just posed to
4 him, and he just answered in that way.

5 MS. ROSE: And that makes -- I just believe that makes
6 it all the more confusing without the full answer.

7 MR. SLATER: Yeah, I don't agree at all, but I'll wait
8 until my turn comes. You're asking me, so I was just
9 responding.

10 SPECIAL MASTER VANASKIE: Well, give me your objection
11 to the balance of the answer starting with "however."

12 MR. SLATER: Okay. First of all, Judge, and -- we
13 sent you our briefs on the designation issues, I think a week
14 or so ago, just so you would have those.

15 SPECIAL MASTER VANASKIE: Yes.

16 MR. SLATER: There's a case that's cited in our brief,
17 which is a Fourth Circuit case, that literally talks to this
18 specific issue, and the parenthetical that we have to that case
19 says that the rule does not require admission of self-serving,
20 exculpatory statements made by a party which are being sought
21 for admission by that same party.

22 So the first argument that I have is all this is, is a
23 self-serving, exculpatory statement that he threw in because he
24 wanted to say, yes, that's true, and that is important, but let
25 me tell you why it doesn't matter.

1 So what he's doing is essentially acting like a lawyer
2 and saying it doesn't matter. There's a second reason -- we
3 already know it's not responsive because all he was asked is
4 whether or not -- that's why it's important to conduct a prior
5 risk assessment, so you'll figure it out what we should be
6 looking for.

7 The second reason is, if you look at his answer, he
8 says: However, from the perspective of the knowledge at that
9 time, FDA or the whole pharmaceutical industry did not have any
10 knowledge of this impurity.

11 He's not a designated expert. He wasn't asked what
12 does the industry know, what does the FDA know. That's an
13 expert opinion that he wasn't asked about to now throw in this
14 self-serving, exculpatory opinion, which is really in the realm
15 of not factual. He's hasn't laid a foundation for it at all.
16 He is just asserting in what would be a net opinion that any
17 expert would get thrown out on if they don't actually support
18 it with an adequate foundation, and he just throws that in
19 there as a self-serving, exculpatory statement.

20 And you're going to see, as we go through this, he did
21 it a lot. The same phrase kept coming up. I am sure you've
22 seen that. So for that reason, we don't think that that
23 non-responsive part of the answer, which is a self-serving,
24 exculpatory statement, which is more akin to expert testimony
25 and would then be a net opinion, even if it was an expert. For

1 all those reasons, we ask that the designation be stopped, as
2 we suggested, "judging from the sentence, I agree it is
3 important," period.

4 Thank you, Your Honor. And I intend to follow the
5 rule from the other day of we talk once.

6 SPECIAL MASTER VANASKIE: Thank you. Nina, we will
7 give you rebuttal.

8 MS. ROSE: Thank you.

9 Your Honor, this sentence of the perspective of the
10 knowledge at the time the FDA and the pharmaceutical industry
11 did not have any knowledge, that is established. The FDA
12 issued press releases stating in 2018, after the recall, that
13 regulators and the industry did not expect these impurities to
14 be in valsartan.

15 This isn't an expert opinion. This isn't him going
16 outside. He's talking about the facts on the record.
17 Plaintiffs have asked all of these questions. Repeatedly, we
18 hear these arguments that this isn't what the documents say,
19 I'm allowed to ask questions of witnesses based on what the FDA
20 has said or what's in the regulations.

21 It can't be a one-way street. It can't be that
22 plaintiffs can ask inflammatory questions saying it's based on
23 FDA statements and then say that a witness can't explain when
24 he's talking about the risk assessment, based on what the FDA
25 itself has said, that no one knew and no one knew to look for

1 it.

2 And this is just a constant theme for plaintiffs'
3 designations, is cutting out one sentence they like. If at
4 trial these witnesses would have been able to provide
5 explanatory comments, I don't think that this would have been
6 stricken, this answer. It's right in the same vein as all of
7 the other questions that plaintiffs have designated.

8 SPECIAL MASTER VANASKIE: Yes, the problem is that he
9 didn't need to throw that in to give a complete answer to the
10 question. And you're going to put in evidence to show that it
11 was not known that NDMA could be created in this manner. I
12 just didn't think it was necessary for this witness to repeat
13 that mantra throughout his testimony.

14 So I will sustain plaintiffs' objection and strike the
15 testimony from page 81 towards the end of line 24 through
16 page 82, line 5.

17 I think the next excerpt is at page 139. It starts
18 at -- so the designated testimony is from 139 --

19 MR. SLATER: We don't object. That's fine. We'll
20 agree to that one. That counter we'll agree to.

21 SPECIAL MASTER VANASKIE: Okay. That's the counter at
22 138-18 to 139-6. Correct?

23 MR. SLATER: Yes, Your Honor.

24 SPECIAL MASTER VANASKIE: All right. That counter is
25 agreed to.

1 Next we go to 163, line 12.

2 MR. SLATER: My position would be the same as the
3 first designation, the same argument.

4 MS. ROSE: Your Honor, if I may respond?

5 SPECIAL MASTER VANASKIE: You may respond, Nina.

6 MS. ROSE: I think that in this situation, there's
7 even more of a reason to include the testimony. Plaintiffs are
8 cutting off the beginning of the answer that explains exactly
9 why they did not do the testing. I think this is extremely
10 misleading if plaintiffs are allowed to cut off the beginning.
11 This isn't something that was thrown in at the end. It is the
12 basis for the answer. So I think this is a different scenario
13 than Your Honor's last ruling.

14 SPECIAL MASTER VANASKIE: I'll give you an opportunity
15 to respond, Adam.

16 MR. SLATER: Thank you, Judge.

17 This is emblematic of the massive difficulty we had in
18 these depositions with getting witnesses to actually answer
19 questions directly, and I know I mentioned it during our first
20 hearing, but just to make sure that I reiterate it because it's
21 relevant here.

22 I was moving to strike answers left and right, and
23 Your Honor actually directed me not to move to strike anymore
24 because you said they're preserved, and that was fine. If this
25 answer had been given and I hadn't been told or

1 George Williamson hadn't been told not to move to strike, would
2 have moved to strike the answer as non-responsive and would
3 have said the first part is not responsive, the second part is.
4 And this was -- frankly, it made it more difficult for us
5 because it made it harder for us where they would throw in the
6 non-responsive part first and then say, yeah, but you're right,
7 we never did the test.

8 They don't get rewarded for making the answer
9 non-responsive and flipping it -- usually someone says "yes,
10 but" or "no, but," but here they actually started with the
11 "but" first, but they shouldn't be rewarded for that, and only
12 the responsive part of the answer should be included. Because
13 again, we were not able to move to strike during the deposition
14 and go through that process because the defendants -- ZHP's
15 counsel at the time, he asked us not to. So we did not do it,
16 and we didn't realize there was such an issue.

17 That's responsive to the question. The first part is
18 that exculpatory talking point that nobody asked about in that
19 question. It was a simple question, "did you do the test or
20 not?" And that's all we asked and that's all the answer should
21 be.

22 SPECIAL MASTER VANASKIE: Let me ask you a question,
23 Adam.

24 Yes, I instructed you not to move to strike to move
25 the depositions along, but you have the opportunity now to

1 argue your point on these designations.

2 So were you prejudiced by that?

3 MR. SLATER: I think Your Honor's ruling was, to
4 alleviate the prejudice, you said, look, we are going to treat
5 this as if you did move to strike.

6 SPECIAL MASTER VANASKIE: Right.

7 MR. SLATER: So I think that following that protocol,
8 I -- I think it would have been more optimal for us to be able
9 to say move to strike so that the defense lawyer would have
10 been on notice to say, you know, why don't you ask the question
11 again because they knew their client didn't answer properly.

12 But that's only one of the only things we could have
13 done. But I'm certainly not quibbling with your ruling from
14 what was happening during the depositions. I think what you
15 did was a reasonable measure to make the depositions more
16 expedient, which we were doing late at night by Zoom, and it
17 made sense.

18 And since Your Honor said we would take it up as if,
19 I'm arguing as if we moved to strike because we obviously would
20 have if this had just been in a case where that type of a
21 ruling was not in place.

22 So I'm certainly not criticizing Your Honor's ruling.
23 What I was doing was more giving the background just to
24 reiterate again for the record and for everyone who's involved,
25 including counsel now who wasn't involved at the time, of what

1 was happening during the deposition. And to say it's unfair to
2 knock out the first part of the answer, my answer would be,
3 well, it's unfair to throw in a non-responsive talking point up
4 front and make it harder for us to get to a responsive answer,
5 which was an incredibly hard task with most of the witnesses
6 that we deposed.

7 SPECIAL MASTER VANASKIE: Nina, brief response?

8 MS. ROSE: Sure. I think that what Adam is trying to
9 say is that he is able to cut up these answers as he sees fit,
10 but the question is being answered by the witness, and the
11 witness is explaining the answer. This is not a long colloquy.
12 This is not a talking point.

13 This is explaining why that there was no testing on
14 this peak for nitrosamine specifically, because there was no
15 understanding that nitrosamines could be present. And that's a
16 fair response. I don't think that's -- my quarrel with it
17 isn't that counsel didn't move to strike at the time. I
18 haven't raised that.

19 My issue is that this is the full answer, and it is
20 misleading to cut up a witness's answers in this way.

21 SPECIAL MASTER VANASKIE: Yes, I will allow the
22 counter-designation to stand.

23 So the question would start at line 6 of page 163, and
24 your counter-designation at 163, lines 9 and 10 and 163,
25 line 11 would stand. The answer would come in. Then lines 12

1 through 14 would come in.

2 All right?

3 MS. ROSE: Thanks, Your Honor.

4 SPECIAL MASTER VANASKIE: Let's go to page 168. This,
5 again, deals with a counter-designation. Adam, this one I'm
6 inclined to disallow the counter-designation starting at
7 line 17 going to line 23.

8 I just didn't know why he needed to throw that in,
9 when we used GC-FID for the testing. The response of NDMA was
10 pretty low, et cetera.

11 Why is that necessary, Nina?

12 MS. ROSE: Thanks, Your Honor. So this really -- the
13 counter-designation relates to explaining the temporal scope of
14 what was known and what could be known at the time the testing
15 was being performed based on the type of testing.

16 So the question is asking about NDMA eluting near the
17 toluene peak in residual solvent gas chromatograms of ZHP's
18 valsartan API. So post 2018, when GCMS was being used to
19 evaluate whether NDMA was present, this is something that you
20 could see in the peak. You could see where the peak is --
21 where NDMA is present.

22 But during the time that valsartan was on -- was being
23 developed and was on the market, ZHP was using, consistent with
24 the valsartan monograph, GC-FID testing, and that's a different
25 type of testing. The witness here is explaining that when

1 GC-FID testing was used, consistent with what the standards
2 require to be used, there was no way to accurately determine if
3 something was NDMA because it was not picked up by the GC-FID
4 testing.

5 So this is really just explaining -- it's the witness
6 explaining, yes, after 2018, we know that that's where the peak
7 is; but prior to 2018, we didn't because GC-FID testing
8 wouldn't have picked it up.

9 And then the next designated testing then talks about
10 GCMS and Novartis using it, so it kind of clarifies when GCMS
11 was being used, yes, you could see the peak; but prior to 2018,
12 when GC-FID was being used, you couldn't see the peak. So it's
13 really just explaining the two different types of testing,
14 which is a key piece of the evidence in this case.

15 SPECIAL MASTER VANASKIE: Adam?

16 MR. SLATER: Okay. First of all, the only question
17 was where the NDMA peak is. It didn't ask why you didn't see
18 it on certain testing or others. He threw in "this is what we
19 understood after 2018." Not even what he was asked, but I
20 designated it anyway.

21 I need to address -- although I don't think this helps
22 counsel, the fact that they're trying to distinguish between
23 the different types of testing, I don't think that gets them in
24 to make this responsive because the question was very narrow
25 and it was answered and that was it.

1 And again, I let in -- I agreed to the "after 2018"
2 part, which really doesn't matter, but he put in that that's
3 when they got their understanding.

4 But I do want to clarify one thing, Judge. What
5 counsel just said about what testing was available is
6 completely inaccurate. It's completely contradicted by the
7 testimony from the witnesses. For counsel to just tell you
8 they never used GC mass spectrometry -- counsel is nodding her
9 head, but she just said GCMS wasn't used until 2018. We
10 literally have documents and testimony that GCMS was available
11 and being used at CMAT for years before 2018. And, in fact, we
12 have testimony that CMAT, which is where Jinsheng Lin worked,
13 the analytical laboratory, was using GCMS to evaluate valsartan
14 impurities in July of 2017, which is not a big surprise because
15 that's when he wrote his email.

16 So I'm not saying that because I think this is a
17 legitimate argument to get this testimony in. I just want the
18 Court to know that what counsel just told you, that only GC-FID
19 was used, is just completely inaccurate. And they've already
20 acknowledged that GCMS was available, and if they had used it,
21 they would have found it; and they had the machines going back
22 to at least 2013.

23 So again, I wanted you to know factually what the
24 accurate evidence is in the record. But again, this testimony
25 that they're trying to add in is not what was asked. The

1 question was extremely narrow. Where was the NDMA located?
2 And he agreed, yes, as of 2018, we know that.

3 So he even got in "we didn't learn this until later."
4 But the rest of it -- I think your first impression was the
5 right one, that the rest of it is not responsive and we ask to
6 not include it.

7 SPECIAL MASTER VANASKIE: Nina, I'll give you brief
8 rebuttal.

9 MS. ROSE: Thank you. I appreciate that.

10 I think Mr. Slater's suggestion that I was attempting
11 to mislead the Court in any way about the evidence in this case
12 is completely unfounded. I was trying to make the point that
13 there are two methods of testing, GCMS and GC-FID. And as I
14 said, GC-FID is what is listed in the valsartan monograph as
15 the residual solvent testing that should be used when testing
16 valsartan.

17 The fact that GCMS was available to ZHP, that they
18 used it at some point, that is not relevant to our discussion
19 here. I'm just trying to explain that what the witness is
20 saying is that there are two types of testing, GC-FID, GCMS.
21 They were using GC-FID to test, consistent with the valsartan
22 monograph. And what -- the NDMA peak was not showing up on
23 GC-FID.

24 I in no way was intending to suggest to the Court that
25 GCMS was not available to ZHP, that CMAT didn't use GCMS. That

1 was not the point. We're just talking about this witness's
2 answer and what the witness was trying to explain about the
3 temporal scope and the type of testing that was being used.

4 But I apologize if I was in any way inaccurate in my
5 statements. I was not intending to be.

6 SPECIAL MASTER VANASKIE: The bottom line for me is
7 that Mr. Li was not asked about testing methods for purposes of
8 explaining that the NDMA elutes near the toluene peak in the
9 residual solvent, and so all of that answer that comes 2018
10 seems to me to be gratuitous, self-serving, and I will strike
11 the testimony starting with "when we used" on line 17 of
12 page 163, through line 23.

13 Now I think we can move to page 195.

14 (Court reporter interruption.)

15 SPECIAL MASTER VANASKIE: So we're up to page 195 of
16 Mr. Li's deposition. And I take it the issue here is with
17 respect to the counter that starts on page 197, line 12.

18 So the answer -- the designation from the plaintiff
19 concludes at 196, line 19.

20 And then, Nina, you want to designate the colloquy or
21 the exchange that occurs on page 197, line 12 to page 198,
22 line 6. Explain to me why that's necessary for completeness
23 purposes.

24 MS. ROSE: Sorry, Your Honor, give me one second
25 because I don't have the --

1 SPECIAL MASTER VANASKIE: Yes, it's hard.

2 MS. ROSE: I don't have this counter marked in my
3 transcript, so I want to make sure there wasn't a clerical
4 error here.

5 SPECIAL MASTER VANASKIE: Okay.

6 MS. ROSE: Your Honor, I think we can drop this
7 counter. I think there was a misunderstanding that the
8 question at 195, 20 to 22 was designated, so I think we can
9 drop this counter.

10 SPECIAL MASTER VANASKIE: All right. So stricken is
11 the question that starts on line 12 of page 197 through the end
12 of the answer on page 198 at line 6.

13 MR. SLATER: Can I ask a question, Nina?

14 MS. ROSE: Sorry.

15 MR. SLATER: You might have misspoken on what page you
16 were talking about.

17 MS. ROSE: Maybe. So my question is page 196, are
18 lines 20 through 22 designated?

19 MR. SLATER: Mike would have to answer that, who's on.
20 Because I don't have our full designations because you guys
21 have been clipping them.

22 SPECIAL MASTER VANASKIE: I do not have that as
23 designated.

24 MR. SLATER: Yes, I don't either.

25 MS. ROSE: It might not be on the part that Your Honor

1 has because these are just the designations that we are
2 contesting, so that's why I just want to make sure.

3 SPECIAL MASTER VANASKIE: So you might have to answer
4 that.

5 MR. SLATER: Mike, are you on? Can you tell us? I
6 don't think it's designated, but can you tell us, please?

7 MR. GRIFFITH: You said, Nina, what was the
8 designation?

9 MR. SLATER: 196, line 20 to 22. Is that one
10 designated? I don't think so.

11 MR. GRIFFITH: No. We thought that 196, line 19, the
12 next designation is 198.

13 MR. SLATER: 198, line 7. Okay. So that was not
14 designated?

15 MR. GRIFFITH: Correct.

16 MR. SLATER: Thank you. It's good, Judge, that we can
17 contact people that actually know what we're doing. Now you
18 see who the puppeteers are on us. At least on me. I won't put
19 Nina in that category.

20 SPECIAL MASTER VANASKIE: I think we're ready to move
21 now to page 198, line 7 to 11.

22 MR. SLATER: Yes.

23 SPECIAL MASTER VANASKIE: That's a question. And then
24 the answer comes in at 198, 18 and 19.

25 MR. SLATER: Right. Because the first part was -- I

1 won't say anything. I'll wait until it's my turn. I don't
2 want to lose my turn.

3 SPECIAL MASTER VANASKIE: Well, I think you know me
4 enough that nobody's going to lose their turn. I'm just trying
5 to move it along.

6 (Laughter.)

7 MR. SLATER: No, I am too, Judge. That's why I'm
8 trying to follow the rules.

9 SPECIAL MASTER VANASKIE: Okay.

10 MS. ROSE: Your Honor, I think I can shortcut this.
11 The objection at 198-7 to 198-11 can be dropped. And I think
12 the real issue is the row below, 198-18 to 198-19. This is the
13 answer being cut up.

14 So that was the question. 198, 7 to 11 is the
15 question, and the real objection is to the answer being cut at
16 198, 18 to 19.

17 SPECIAL MASTER VANASKIE: You want to include 198,
18 line 12 through 17, I take it?

19 MS. ROSE: Yes.

20 MR. SLATER: Or through 18, I think you wanted,
21 actually.

22 MS. ROSE: Sorry, 198-12 to 19.

23 SPECIAL MASTER VANASKIE: All right. Let's get this
24 clear.

25 MR. SLATER: You want me to walk through it, Judge?

1 Judge -- not to argue it, but just to clarify what testimony
2 we're designating?

3 SPECIAL MASTER VANASKIE: Yes, walk through it.

4 MR. SLATER: So the designation is the question from
5 lines 7 to 11 where we asked: Can you answer sitting here
6 today whether or not ZHP performed any testing on these unknown
7 peaks to identify whether any nitrosamine impurities existed in
8 these peaks?

9 So we're just asking did you do a test, did you test
10 for that.

11 He then answers, and we designate only the responsive
12 part, which is on lines 18 and 19, where he says: We did not
13 perform the relevant work.

14 Because they didn't test for it, we knew that. What
15 he does is he -- I won't start -- so we did not designate and
16 we object to the answer starting on line 12 that says, "as I
17 mentioned many times regarding this issue previously," all the
18 way through the word "therefore" on line 18.

19 Because we believe that was non-responsive. So I just
20 wanted to clarify for you what is at issue.

21 SPECIAL MASTER VANASKIE: All right. Nina?

22 MS. ROSE: Sure, Your Honor.

23 So this is similar to designations that we've
24 discussed where plaintiff is selectively cutting out parts of
25 the witness's answers and just grabbing a few words that they

1 like.

2 We had -- in making this designation, I wanted to be
3 clear. We had countered with the entirety of the answer with
4 the exception of the reference to the European union, given the
5 Court's rulings that foreign regulatory issues should not be
6 included. So I just wanted to make that clarification.

7 SPECIAL MASTER VANASKIE: No, I will disallow the
8 designation on page 198 from line 12 through the word
9 "therefore" on line 18, and allow the plaintiffs' designation
10 to stand. Again, it wasn't necessary to answer this question.

11 Now are we up to page 314?

12 MR. SLATER: Yes, we are, I think -- I believe, Your
13 Honor. If all that's at issue -- if the objection is not at
14 issue and it's just the counter of 314, 18 to 22, we will agree
15 to the counter and we'll withdraw our objection to the counter.

16 SPECIAL MASTER VANASKIE: All right. Nina?

17 MS. ROSE: Let me look at that for one second, Your
18 Honor.

19 SPECIAL MASTER VANASKIE: Yes, it's going to take me a
20 while to...

21 MS. ROSE: Okay. That's fine, Your Honor.

22 SPECIAL MASTER VANASKIE: So the record is clear then,
23 what have you just agreed to?

24 MS. ROSE: I believe we just agreed that the counter
25 at 314, 18 to 22 would come in, and defendants will drop their

1 objection to the plaintiffs' designation at 314, 4 through 17.

2 SPECIAL MASTER VANASKIE: You agree, Adam?

3 MR. SLATER: I do, Your Honor.

4 SPECIAL MASTER VANASKIE: All right. I think we're
5 now up to 317, lines 6 through 23.

6 MR. SLATER: I can tell you, Judge, part of their
7 counter is 317, 3 to 5. We will agree to that counter. I
8 would like to assume that they're going to drop their objection
9 because I think it's the same line of questioning as the prior
10 one. But we're not going to contest and we'll agree to the
11 317, 3 to 5 counter.

12 SPECIAL MASTER VANASKIE: All right. That's 317,
13 3 to 5 is part of the question.

14 MS. ROSE: Your Honor, can I just give the short
15 explanation of the context for this?

16 SPECIAL MASTER VANASKIE: Sure.

17 MS. ROSE: Thanks. So the previous counter on
18 page 314 that we just agreed not to contest, this all relates
19 to a very technical discussion of where the NDMA peak that was
20 ultimately discovered in 2018, where it shows up on a
21 chromatogram and whether it's near or is the same as the peaks
22 that were identified by customers, the unknown peaks while
23 valsartan was on the market. And the witness is trying to
24 explain that where the NDMA peak, while it's near some of the
25 other peaks that were identified, it's not the same peak.

1 So I'm just trying -- it's confusing testimony and
2 it's very technical. So I think the whole answer needs to come
3 in at 317. I'm willing to drop the objection because the
4 witness is trying to explain where the NDMA peak is likely to
5 be and trying to explain whether you would see it or not see
6 it, like where would it be? Because the whole line of
7 questioning --

8 MR. SLATER: I agree.

9 SPECIAL MASTER VANASKIE: All right. Very well.

10 MR. SLATER: I'll agree.

11 SPECIAL MASTER VANASKIE: So all of that will come in
12 then.

13 MR. SLATER: Okay. The counter is in also?

14 SPECIAL MASTER VANASKIE: Yes.

15 I think we can move to page 387 now. The designation
16 is at page 387, line 4 through 9, ending with "I don't know."

17 The question is: This email was sent on May 22, 2018.
18 Do you know of any emails that Novartis sent to ZHP earlier
19 than May 22nd of 2018 about unidentified peaks in ZHP" -- as
20 designated.

21 They want to include as part of the answer: I'll be
22 more clear about it if I am presented with a corresponding
23 document.

24 Did you want to elaborate on your position, Nina?

25 MS. ROSE: Sure, Your Honor. So, again, this is a

1 very -- this is just including the witness's full answer for
2 context. Counsel had asked the witness if they're aware of any
3 email sent by Novartis prior to May 2018 about unidentified
4 peak. The client is making clear -- that's a very broad
5 answer. The client's making clear I don't know off the top of
6 my head, but if you have a document you want to ask me about --
7 kind of clarifying it. There's a particular document you want
8 to ask me about, then I'm happy to look at it. Counsel does
9 not present them with a document.

10 So it's a question here of just clarifying what the
11 witness said. The witness didn't say "I don't know," the
12 witness said if you give me, you know, a document or evidence,
13 I'm happy to clarify. I just think, once again, this is the
14 context of the witness's answer. And cutting up the witness's
15 answer, it doesn't really serve anything. It's one line. It's
16 not going to, you know -- it's not a long colloquy. This is
17 just what the witness said and the witness's answer.

18 And I think plaintiffs have multiple times said that
19 what a witness says or how they say it is relevant to their
20 veracity, and I think that's part of this, that if you're
21 cutting up a witness's answer, the jury isn't seeing how the
22 witness actually answered the question.

23 SPECIAL MASTER VANASKIE: Adam, did you want to
24 respond?

25 MR. SLATER: Sure, Judge. This was a 30(b)(6) witness

1 and we were trying to learn information from him. And the
2 letters that we were aware of that went from -- or emails that
3 went from Novartis to ZHP, we're aware of the May 22nd, 2018,
4 and it was our understanding that was the first one.

5 So we're asking this witness, who is the 30(b)(6)
6 witness for the company on this subject, is there anything
7 earlier than that. We're not aware of any such thing. So he
8 says, I don't know. That's his answer, he doesn't know. And
9 then he throws in, he'll be more clear if presented with a
10 corresponding document. I'm not aware of a corresponding
11 document showing them complaining about the peaks earlier than
12 that.

13 For him to throw in uncertainty about whether or not
14 there really is something out there injects uncertainty that
15 suggests that there's some documents out there he wasn't shown
16 that would change his answer. We don't have such a document.
17 Counsel for the defendant could have shown him another document
18 later and said, well, here's a document from 2015 when Novartis
19 was complaining about this. And then we would have said,
20 great, now we know it started earlier.

21 But it's not necessary. We asked him a
22 straightforward question, and now he's qualifying his answer by
23 saying, well, if you show me a document, then I'll give you a
24 better answer. Well, I mean, people could say that to every
25 single question they're asked during a deposition. It doesn't

1 add anything.

2 SPECIAL MASTER VANASKIE: No, I will allow it. And
3 I'm allowing it because the witness answered "I don't know" and
4 said, well -- but maybe I -- you know, this is five years ago
5 or whatever it is, three years ago. The answer "I don't know"
6 may be suspect if I'm shown a particular document. So I think
7 it's appropriate and we'll allow it.

8 MR. SLATER: Can I ask a question, Your Honor? And
9 I'm not looking to reargue your decision.

10 SPECIAL MASTER VANASKIE: Yes, sure.

11 MR. SLATER: I'm going to ask counsel, because they've
12 put this testimony in where he's suggesting there is such a
13 document. I'm asking counsel, is there a document you're aware
14 of where Novartis complained about unidentified peaks before
15 May 22, 2018, in the valsartan?

16 I would just like to know if they're making a
17 representation and there are such documents. I'm not aware of
18 it.

19 MS. ROSE: I can answer Mr. Slater's question. I'm
20 also not aware of it, and that's not our point. I think what
21 you're saying is that we're trying to suggest that there are
22 earlier Novartis documents. I don't know that that is
23 something that would help ZHP's position.

24 This is really just -- as Your Honor said, this is the
25 witness explaining, I don't know, this is many years ago,

1 you're asking me in perpetuity -- like, going back in time, was
2 there ever an email from Novartis. And the witness is saying,
3 I don't know, if the document comes -- like, you show me a
4 document, then I can talk about it.

5 But I think Your Honor is exactly on point, it's just
6 explaining the witness's answer given the time frame and the
7 scope of the question.

8 SPECIAL MASTER VANASKIE: Let's move to page 433. The
9 designation is at line 433, line 19 to 434, line 9.

10 And you have an objection, Nina, to excluding the
11 beginning of the question: Hindsight is very clear, isn't it?

12 MS. ROSE: 433-18. Yes, Your Honor. Because -- I
13 would like to include 433-18, which is the beginning of the
14 question and lays the --

15 MR. SLATER: That's fine. I thought we were helping
16 them. I figured they didn't want it in. If they want that in,
17 we're happy to add it in. You got it, 433, 18 to 19 is in.

18 MS. ROSE: And then 434, it's the full answer. And
19 again, this is our -- this is the witness's answer. This is
20 what the witness is explaining.

21 SPECIAL MASTER VANASKIE: So you want to add in 434,
22 line 9 through 13, the analogy he uses with the stars, the
23 Milky Way?

24 MS. ROSE: Yes. The question is referring to the fact
25 that nitrosamine impurities were present, which is not

1 contested, there were nitrosamine impurities in the product.
2 But the witness is trying to explain the answer that because
3 something exists in the product, if you don't have the
4 technology and you don't have the reason to look for it, then
5 that doesn't -- you don't have a reason to investigate. And
6 he's just starting to explain the context of his answer.

7 His analogy is there's stars that we don't know about
8 now and in the future we might find new stars, but that's
9 because that's how science works; you're always advancing,
10 you're finding new things, and you can only work on the
11 information you have available at the time.

12 SPECIAL MASTER VANASKIE: Do you want to respond,
13 Adam?

14 MR. SLATER: Sure. The question simply was that the
15 peak was there and it could have been found. And he admits it.
16 Yes, it's true that they were there.

17 For him to now throw in some inapposite expert
18 testimony analogy to the stars and the Milky Way that doesn't
19 even fit this case, which he wasn't asked about -- he wasn't
20 asked why didn't they find it, he wasn't asked is that like the
21 Milky Way?

22 It's just, again, another self-serving, exculpatory
23 talking point to try to make it seem like, hey, you know what,
24 nobody knows what stars are in the sky. It doesn't add
25 anything. The question was very narrow just to get him to

1 admit that the peak was there to be found, and I don't think
2 that we need to hear about the Milky Way.

3 SPECIAL MASTER VANASKIE: Yes, I agree. I don't think
4 it was necessary to complete his answer and, therefore, will
5 sustain plaintiffs' position and strike the testimony on
6 page 433, line 9 starting with the word "however," continuing
7 to the end of the answer on line 13. And I think that
8 completes this witness.

9 MR. SLATER: Yes, it does, Judge.

10 SPECIAL MASTER VANASKIE: Okay. All right. I'd like
11 to move now to Peng Dong. Give me a minute to find it.

12 All right. Sorry. I had all this lined up, I
13 thought.

14 Let's take a five-minute break while I locate the
15 transcript.

16 MR. SLATER: Okay.

17 SPECIAL MASTER VANASKIE: Thank you.

18 (Brief recess taken from 10:53 a.m. to 10:58 a.m.)

19 SPECIAL MASTER VANASKIE: All right. We're starting
20 with Peng Dong's testimony given on March 30th, 2021. And the
21 first contested area starts at page 164 of his testimony. And
22 the designation is from page 164, line 11 to 165, line 7. And
23 you have an objection to this, Nina?

24 MS. ROSE: Yes, Your Honor. I think the issue here is
25 that the question that was asked -- there were two questions

1 asked, with the second question superseding the first. So the
2 last part of the question that was asked of the witness was:
3 Did anyone at ZHP know that it was possible, between 2011 and
4 June of 2018 -- and he's referring to the possibility that DMF
5 could decompose.

6 And the witness answered: That's a fair -- this
7 wasn't a did ZHP know, is it the official position that ZHP
8 knew? It was, did anyone at ZHP know, which calls for
9 speculation as to what every single person knew or has ever
10 learned or whatever.

11 So the witness makes this clear: I'm not able to
12 provide an accurate response to this question.

13 And then goes on to explain maybe someone at one point
14 learned this, maybe it popped into their mind in a different
15 context. He's kind of just speculating to explain, but I can't
16 tell you what every single person at ZHP knew.

17 So the entire line of questioning is based on calling
18 for speculation from the witness and the witness goes on to
19 just speculate. Again, I think this was a language issue where
20 the witness is trying to explain and giving examples. The
21 whole line is misleading and sort of irrelevant because a
22 witness cannot say what every single person at ZHP ever knew or
23 didn't know.

24 SPECIAL MASTER VANASKIE: Adam?

25 MR. SLATER: Yeah, Judge. He's a 30(b)(6) corporate

1 representative speaking for the company. He was one of the
2 hardest witnesses I've ever deposed in my life to get a
3 straight answer from. He's the witness that we had to bother
4 Your Honor twice for hearings during the deposition because we
5 could not get straight answers.

6 So this question falls directly within topic 11 of the
7 designations which were court ordered. ZHP's evaluation of the
8 potential risks to the purity of contents of ZHP's valsartan
9 API posed or caused by solvents used during the manufacturing
10 process, et cetera.

11 It's absolutely squarely within the designation. He
12 could have answered any way he wanted. What he could have done
13 was he could have just limited his answer to, I did not see any
14 documentation. Because we know the answer, too. We don't sit
15 here in a vacuum today. We know they did nothing to evaluate
16 this issue. They've actually stipulated to that.

17 So if he had just said I haven't seen any
18 documentation, I would be fine. He wanted to throw in all this
19 other stuff. That's fine. If he wants to be evasive, he can
20 be evasive, the jury can see it and can see that their 30(b)(6)
21 witness was evasive or not. Maybe they think he did have a
22 dream, I don't know, someone had a dream, but that was his
23 answer. And it's squarely within the designation and it's not
24 speculative, it's what he was court ordered to answer.

25 SPECIAL MASTER VANASKIE: Yes, I would overrule the

1 objection and allow the question and answer to stand. So that
2 designation will come in.

3 The next area I have is at page 169, line 20 to
4 page 170, line 18.

5 MS. ROSE: Your Honor, if I could hopefully
6 streamline --

7 SPECIAL MASTER VANASKIE: Go ahead.

8 MS. ROSE: -- this. So we included this -- we want to
9 preserve our objection. We recognize Your Honor has previously
10 ruled that scientific articles or publications discussing the
11 formation of -- or sorry, I apologize -- discussing DMF
12 indegradation could come in. We object that they're hearsay
13 documents that aren't relevant to notice.

14 But Your Honor has previously indicated these can come
15 in. So there are a variety of objections on this witness with
16 respect to this hearsay objection, I think go through page 172.

17 SPECIAL MASTER VANASKIE: All right. So those were
18 objections made for purposes of preserving your record.

19 MS. ROSE: Yes, Your Honor. It goes to the issue --
20 (Simultaneous speakers.)

21 SPECIAL MASTER VANASKIE: It's noted. So that --
22 those designations will be played for the jury unless Judge
23 Bumb decides otherwise. All right?

24 And that takes us now to page 191. And this is -- the
25 objection is to the counter, although there is an objection to

1 the designation as well.

2 MR. SLATER: I think the whole objection goes to the
3 defendants asking that the whole answer read and our objection
4 to that.

5 Is that correct? I think that's right, Nina, right?

6 MS. ROSE: Yes, that's accurate.

7 MR. SLATER: And so you know, Your Honor, we have the
8 answer ending after he says "It did not identify the potential
9 risk of nitrosamine impurity and valsartan impurity." That's
10 where our designation ends.

11 And then the defense is asking to add the rest of the
12 answer through line 23.

13 SPECIAL MASTER VANASKIE: So at issue is the testimony
14 that's because -- and now I'm quoting: That was because in
15 2011 ZHP did not have any understanding of the risks of
16 creation of nitrosamine in the valsartan zinc chloride process.
17 This is my response disregarding the industry or other
18 companies.

19 Yes, to be consistent with how I've ruled previously,
20 I would not allow the statement made by Mr. Dong starting on
21 page 191, line 18 with the phrase "that was because," and
22 strike that to the end of the answer on line 23.

23 Now I think we move to page 227.

24 MR. SLATER: Just to orient Your Honor, our
25 designation ends on -- the answer is -- after he's asked

1 whether ZHP assessed this question about whether nitrite or
2 nitrous acid might react with dimethylamine as part of the zinc
3 chloride process, the answer that we designated is, "we did not
4 conduct such an assessment," and we stop there. And we didn't
5 designate the part because it's for the same reason as the last
6 one.

7 SPECIAL MASTER VANASKIE: And, Nina, you have the same
8 argument?

9 MS. ROSE: Your Honor, it's essentially the same
10 argument, but I think it's even more important here. Again, we
11 were doing deposition designations. This is a Chinese witness
12 who gave this answer, that they did not conduct an assessment
13 because between 2011 to June 2018 the authorities and industry
14 didn't have an understanding of this.

15 This is testimony that the witness gave that was on
16 the record, and counsel would not have had a reason to follow
17 up and ask that on a direct because the testimony had already
18 been given.

19 So again, this is when we're cutting up testimony to
20 the answer that plaintiffs like, these are unavailable
21 witnesses, and we're not able to include the part of the answer
22 that explains the reasons why.

23 And ZHP's counsel didn't have a reason to ask those
24 questions because the testimony was already in the record. The
25 witness had given the testimony.

1 MR. SLATER: Do I need to respond, Judge, or --

2 SPECIAL MASTER VANASKIE: No. I'm trying to be
3 consistent and I will strike the counter-designation at
4 page 227, after the word "assessment."

5 And I'm doing it because I think the jury's going to
6 know what your position is on this. This witness didn't have
7 to answer beyond "we did not conduct such an assessment" and I
8 think that's -- I think it just clouds the matter to allow him
9 to make that assertion. I'm trying to anticipate, you know, if
10 this was a live witness at trial, Mr. Slater could stand up at
11 the end of the answer and say, I move to strike everything
12 after such a word. And the judge could say, yes, stricken.
13 It's the same thing. So I will strike that.

14 And I think we're moving to his testimony from
15 March 31st. It picks up on page 276. So the designation
16 begins on page 276, line 11 to line 15.

17 And then there was a counter-designation because,
18 again, the designation cuts off the witness's answer. And ZHP
19 wanted to include the testimony from line 16 to line 22.

20 And I think this falls in that same category, Nina. I
21 know you disagree with my ruling, that's fine, but do you
22 disagree that this falls in the same category?

23 MS. ROSE: Your Honor, I agree that it's the same
24 general category and I won't belabor the issue. I understand
25 the Court's ruling, but we want to preserve our objection on

1 this.

2 I think the amount of times that the witness is being
3 cut off and not being able to provide a full answer --

4 SPECIAL MASTER VANASKIE: And your position is
5 preserved.

6 MS. ROSE: Thank you.

7 SPECIAL MASTER VANASKIE: But I will strike that from
8 line 16 to line 22. All right?

9 Now we go to page 340. This is in the same category,
10 I believe.

11 MR. SLATER: It is.

12 MS. ROSE: Your Honor, I think this may be a little
13 different.

14 SPECIAL MASTER VANASKIE: All right. Go ahead.

15 MS. ROSE: So in prior designations that Your Honor
16 has been addressing today, there's been a situation where it
17 was a question where the witness answered, and then Your Honor
18 held that the entirety of the answer included a non-responsive
19 talking point. I assume that's Your Honor's reasoning.

20 Here, the answer directly addresses the fact that
21 between 2011 and 2018 -- sorry, yeah, 2011 to 2018, ZHP did not
22 have an understanding regarding the generation of NDMA.
23 Plaintiffs have designated that. So plaintiffs have designated
24 the portion of the answer that explains ZHP's understanding.
25 They're now just cutting out the portion of the answer that

1 notes that the authorities and the industry also did not have
2 an understanding.

3 That's really not contested in this case. The FDA
4 issued statements saying that prior to the discovery in 2018,
5 neither the industry nor the regulator had an understanding
6 that this could form. So I'm just not clear why plaintiffs are
7 trying to cut up the witness's testimony in this way. That's
8 not a prejudicial statement, it's not a statement that's
9 outside of the scope of the witness's testimony or outside the
10 scope of this case. Again, it just seems bizarre to me to cut
11 up a witness's answer on a relevant point.

12 SPECIAL MASTER VANASKIE: Go ahead, Adam.

13 MR. SLATER: Thank you, Judge.

14 I don't know why it seems bizarre. We do this all the
15 time. We try to find the responsive part and try to put it
16 together. What I think is interesting -- this is the same
17 issue. And we still designated a massive amount of
18 non-responsive parts of his answer because the question is a
19 very narrow, simple question.

20 On line 3: The risk assessment performed by ZHP in
21 connection with the zinc chloride process failed to discover
22 those NDMA levels in those three validation batches, correct?

23 And for the Court's information, the three validation
24 batches were the first three batches they manufactured and used
25 in order to invalidate the process, and it turns out all three

1 of those batches had massive amounts of NDMA in them. So
2 that's what we were talking about now, "When you were doing
3 your risk assessment, those are the batches you did it on, you
4 did not identify the NDMA." Simple.

5 The answer should have been you're correct, because
6 they didn't. Instead, the entire answer is an explanation for
7 why they didn't do it. We left in virtually the whole answer.
8 We left in starting on line 7, none of which was requested.
9 "In 2011, between 2011 and June 2018" -- and then we took out
10 on line 8, "the authorities, the industry or."

11 So the answer continues, "ZHP did not have any
12 understanding," because the question only asked about ZHP's
13 risk assessment. And he says they didn't have an
14 understanding.

15 And then on lines 15 to 22, we also designated that
16 where he gives the full explanation. "During this period of
17 time, due to the lack of knowledge, including the knowledge of
18 analytical methods," et cetera. And then he explains that's
19 why it didn't happen. None of that is really responsive
20 because the question was simply you didn't find it on your risk
21 assessment, but we left everything in.

22 But I think it's a bridge too far to now say ZHP
23 didn't find it but, by the way, the authorities and the
24 industry also didn't because that's not what was asked for.

25 And I'll leave this last thought. I thought it was

1 interesting when counsel said, you know, we keep saying this
2 and you keep knocking it out. Yeah. He keeps throwing this in
3 to every single answer. That's not by accident.

4 So these are talking points, as counsel recognized,
5 that don't belong. So we left in a long non-responsive answer,
6 but we don't think that he also should be able to point to the
7 authorities and the industry as well when they didn't do the
8 risk assessment, ZHP did. Thank you.

9 SPECIAL MASTER VANASKIE: All right. Did you want to
10 respond, Nina?

11 MS. ROSE: Yeah, I just wanted to respond. At no
12 point did I admit that anything the witness said was a
13 non-responsive talking point. I was trying to summarize your
14 arguments and Judge Vanaskie's prior rulings. So I just want
15 to make that clear.

16 Again, what counsel decided to designate of the
17 answer, that is up to plaintiffs. So plaintiffs now saying
18 that they designated all of this non -- what they claim is
19 non-responsive testimony, those are their designations. I'm
20 just arguing plaintiffs trying to cut out a handful of words
21 that is a relevant part of this witness's answer.

22 I think part -- one thing just to note is that part of
23 the question is that ZHP failed to discover, which strongly
24 implies that they were required to discover or they should have
25 discovered. This is something they did not, it's that they

1 failed to. Which indicates to me, and I think what the import
2 of this question is, is there was some obligation or some
3 reason to discover how NDMA formed. And the witness is
4 explaining the authorities, the industry, nobody knew how this
5 formed. This wasn't a failure on the part of ZHP. I think
6 that's directly responsive.

7 SPECIAL MASTER VANASKIE: No, I think that was a
8 talking point Mr. Dong wanted to present throughout his
9 testimony, it wasn't necessary to provide a complete answer to
10 this question. The plaintiff has designated lines 15 to 22,
11 which is helpful for ZHP's position in this matter.

12 But I will sustain the objections that it has as to
13 particular lines of this testimony and will direct that they be
14 stricken. And that's really just the line at page 308. And
15 the line, "in 2011, between 2011 and June 2018, the
16 authorities, the industry," that comes out. "Because ZHP did
17 not have any understanding" stays in. All right?

18 MR. SLATER: Okay.

19 MS. ROSE: Understood, Your Honor.

20 SPECIAL MASTER VANASKIE: Now we go to the testimony
21 from April 1st at page 368. It's contested as to the counter.
22 The testimony -- the answer starts on page 368, line 8,
23 continues to line 13.

24 That testimony is: Okay. In 2011, during the
25 valsartan zinc chloride process change, we conducted impurity

1 analysis and risk assessment based on the requirements of laws
2 and regulations, which included the risk assessment on
3 genotoxic impurities.

4 And then the plaintiff wants to strike the rest of
5 that answer: The work we conducted in 2011 was based on the
6 knowledge of the authorities, the industry, and ZHP.

7 And unless you have some new argument, Nina, I will
8 sustain and strike that testimony.

9 MS. ROSE: Understood, Your Honor. It's -- I think it
10 falls within your earlier rulings.

11 SPECIAL MASTER VANASKIE: And your position is
12 certainly preserved.

13 Now we go to page 378.

14 MR. SLATER: Nina, this relates to the EMA guidelines
15 that were cited in the DMF. I thought that those objections
16 had been dropped?

17 MS. ROSE: It's my understanding that Exhibit 207 is
18 not cited in the DMF, but questions and answers on the
19 guidelines have --

20 (Simultaneous speakers.)

21 MR. SLATER: Well, it's a corollary document. It's
22 literally the explanatory document to the guidelines that are
23 cited in the DMF.

24 MS. ROSE: But it's a separate document that's not
25 cited in the DMF; am I right?

1 MR. SLATER: It's the questions and answers from the
2 European agency about the document cited in the DMF, so I don't
3 see how it can be considered to be something separate that's
4 not within it. It literally explains it.

5 MS. ROSE: Well, I think all of our objections -- I
6 think we can probably shortcut this. All of our objections to
7 this document address, one, the foreign regulatory document
8 issue, but really it goes to general causation. I mean, that's
9 just introduce -- that designation just introduces the
10 document.

11 But if you'll see the rest of our objections through
12 page 385 all relate to the general causation issue. So I think
13 this is something we can just discuss with Judge Bumb when we
14 discuss general causation.

15 MR. SLATER: Okay. So the objection is dropped other
16 than you think this somehow implicates general causation?

17 MS. ROSE: Yes, all the questions with respect to this
18 document.

19 Sorry, to clarify, I think in discussing this with
20 Judge Bumb, the other issue is whether or not this is included
21 within her motion in limine on foreign regulatory information.
22 So we could raise that with her. But the real concern here is
23 the general causation issue.

24 MR. SLATER: I don't want to start to push all these
25 issues to Judge Bumb. I mean, I'd like to get these resolved.

1 These are --

2 MS. ROSE: I think we decided --

3 (Simultaneous speakers.)

4 MR. SLATER: It's funny we're having a conversation
5 while you're sitting there, but hopefully this is helpful. I'm
6 trying to resolve it.

7 The EMA guidelines on the limited genotoxic impurities
8 are specifically cited in the DMF amendment in 2013 when they
9 said, hey, we have this new zinc chloride process and they
10 cited to that as a reference. These are the questions and
11 answers the EMA put out on the interpretation and application
12 of that guideline.

13 So if the guideline is in, their questions and answers
14 about the guideline would -- right? It's a corollary document,
15 it goes together with it.

16 And the witness actually said -- well, I won't get
17 into that. I never thought this was being objected to once
18 that ruling came in. But it literally relates only to a
19 document that the company's already admitted they relied on.

20 MS. ROSE: Your Honor, I think I can shortcut this. I
21 think the issue here is general causation. I'm fine to drop
22 the objection at 378, 17 to 23 on the foreign regulatory
23 guidance issue. All of these questions concern a general
24 causation issue.

25 SPECIAL MASTER VANASKIE: All I had -- so I'm confused

1 now -- is part of a question at lines 17 to 23 at page 378.

2 MR. SLATER: I think the net of this is that the
3 foreign regulatory objection is dropped, but counsel wants to
4 maintain that they think this implicates general causation per
5 what they submitted to Judge Bumb. I'm fine with them
6 preserving that argument.

7 SPECIAL MASTER VANASKIE: All right.

8 So you would like to keep in line 17 to 23 of
9 page 378?

10 MR. SLATER: Yes.

11 SPECIAL MASTER VANASKIE: The confusion is I don't --
12 I'm not sure what the question is.

13 MR. SLATER: The question comes on the next page --
14 this is the foundation where I'm identifying the document.
15 Then I actually just continue, but the court reporter at the
16 top of 379 puts in that the exhibit was marked.

17 SPECIAL MASTER VANASKIE: Right.

18 MR. SLATER: And then I orient to the date of the
19 document and I go through it.

20 SPECIAL MASTER VANASKIE: All right.

21 MR. SLATER: So it's literally -- what was focused on
22 was foundational.

23 SPECIAL MASTER VANASKIE: Okay. Well, depending upon
24 the general causation ruling, the foundational information can
25 come in unless it's all found to be within the general

1 causation matter, prohibited as general causation.

2 Are we up to now page 382, line 14?

3 MR. SLATER: Yes.

4 MS. ROSE: So, Your Honor, I think all of the
5 objections from page 378 through page 384 would relate to
6 general causation. Oh, apologies, 385, line 16 is the end of
7 that line of questioning.

8 SPECIAL MASTER VANASKIE: All right. And your
9 position, Adam?

10 MR. SLATER: I guess it will get argued with Judge
11 Bumb.

12 SPECIAL MASTER VANASKIE: All right.

13 MR. SLATER: But they're in subject to Judge Bumb.

14 SPECIAL MASTER VANASKIE: Yes. Now we're to page 436.

15 MR. SLATER: This is the same issue we've been talking
16 about previously, the talking point issue.

17 SPECIAL MASTER VANASKIE: And do you agree, Nina?

18 MS. ROSE: Your Honor, I agree that this objection is
19 similar to the other objections. Apologies. Let me restate
20 that.

21 I agree that this counter-designation is similar to
22 other counter-designations that Your Honor has said are not
23 permitted that relate to the knowledge of the authorities and
24 the industry during the time that valsartan was being
25 manufactured and sold. So we preserve our objections, but do

1 not have additional argument.

2 SPECIAL MASTER VANASKIE: Yes, the same ruling would
3 apply to these exchanges that start at page 436, line 13 and
4 continue to 436, line 20. So for purposes of giving you all
5 guidance, you can edit the videotape accordingly.

6 MR. SLATER: Okay, Judge.

7 SPECIAL MASTER VANASKIE: Now I think we're up to
8 page 446.

9 MR. SLATER: And I think -- again, just to try to cut
10 through, I think from 446 through 450 is the issue that counsel
11 had acknowledged earlier. So I don't -- do we need to argue
12 this one too?

13 I would think, Nina, it's the same --

14 SPECIAL MASTER VANASKIE: I don't think so. And it
15 was raised to preserve the objection, understanding that it's
16 covered by prior rulings. Unless there's something else that
17 you'd like to say on this one, Nina.

18 MS. ROSE: No, Your Honor. We continue to object to
19 this to preserve the objection as we noted. I don't think we
20 need additional argument on it.

21 I will say that there is a counter that is included at
22 450 -- the designation at 450, line 13 to 450, line 18 that I
23 think we do need to discuss.

24 SPECIAL MASTER VANASKIE: All right. So plaintiff has
25 designated the answer at page 413, lines 13 through 18.

1 And do you want to counter-designate page 450, line 19
2 through page 451, line 3?

3 MS. ROSE: Yes, Your Honor.

4 MR. SLATER: I'm not going to object to that part.

5 SPECIAL MASTER VANASKIE: All right. That's in then.

6 MR. SLATER: Nine to -- yeah. I'm not going to object
7 to it.

8 SPECIAL MASTER VANASKIE: 450, line 19 through
9 page 451, line 3 is in.

10 MR. SLATER: Correct. We're withdrawing our objection
11 to that.

12 SPECIAL MASTER VANASKIE: Now I think we're up to
13 page 529. This is another transcript.

14 MR. SLATER: I'm going to withdraw my objection to the
15 counter at 529-23 to 530, line 1. And I think I already
16 dropped our objection to the other counter.

17 So I think that covers that one, right, Nina?

18 MS. ROSE: Yes, I believe that's correct. So the
19 counter at 529, 6 to 13 is in; and also the counter at 529,
20 line 23 to 530, line 1 is --

21 MR. SLATER: Correct, we're going to drop our
22 objection to that.

23 SPECIAL MASTER VANASKIE: All right. So that takes us
24 to 556. Again, the counter is contested here.

25 So you've designated through line 19 on page 556.

1 Adam, I should say, you designated lines 15 through 19. And
2 then there's -- you're contesting the counter at page 556,
3 line 20 through page 557, line 1.

4 MR. SLATER: Correct.

5 SPECIAL MASTER VANASKIE: All right. Nina?

6 MS. ROSE: Your Honor, this is not the same issue as
7 we've raised before, but it is an answer that has been cut off
8 where the witness is explaining here a document that's put
9 before the witness. The witness confirmed -- counsel reads a
10 line from the document to confirm what it says, but the witness
11 is giving context here that the witness is not familiar with
12 the document, the reasons for the research project that's
13 addressed in the document, and that he cannot confirm what the
14 meaning was of the contents of the document.

15 I don't think it's prejudicial, I don't -- it's not a
16 waste of time, it's just the witness explaining this document
17 that's shown to him and that he does have familiarity with it.

18 SPECIAL MASTER VANASKIE: Adam?

19 MR. SLATER: Again, as corporate representative, I
20 asked him a very narrow question, to confirm what this document
21 said. And on lines 15 to 19 he confirms what the document
22 says.

23 And one of the challenges we had in these depositions
24 was to make sure that we could establish through testimony from
25 the witnesses who were designated what their Chinese language

1 document said. So we got him to confirm, yes, this says what I
2 had understood from our support people with the ability to read
3 the Chinese language told us. He then throws in his own
4 knowledge about the background and basis of the collaboration
5 agreement.

6 That's -- first of all, he's designated to deal with
7 this, so him trying to say I don't really know what I'm talking
8 about isn't helpful and he's a 30(b)(6) witness. He then
9 reiterates on line 22 to 23, I can only tell you what it says
10 here in Chinese, which is what I asked him and which he already
11 answered from lines 15 to 19.

12 And then when he says he can't confirm the research
13 objectives and contents. Again, that's superfluous. A, he's
14 supposed to know it as a corporate rep; B, that's not what I
15 asked him.

16 So we'd ask to just stop the answer at line 19 and not
17 go into the non-responsive part at line 20 to page 557, line 1.

18 SPECIAL MASTER VANASKIE: Yes, I will sustain the
19 objection and strike the testimony on page 556, line 20 to
20 page 557, line 1.

21 And I think we're up to page 566.

22 MR. SLATER: We are.

23 SPECIAL MASTER VANASKIE: So you've designated from
24 page 566, line 15 through 567, line 18. And I take it there's
25 no objection to that designation?

1 There is, however, an objection to the counter at
2 lines -- the continuation of the answer at lines 19 through 23.

3 Again, the statement there: This report was created
4 based on the fact that in 2011 the industry or ZHP had no
5 knowledge of the formation of nitrosamine impurities in
6 valsartan zinc chloride process.

7 And to be consistent with prior rulings, I will strike
8 that testimony.

9 MR. SLATER: I think that's it for Peng Dong, Judge.

10 SPECIAL MASTER VANASKIE: Yes, I think that is it for
11 Peng Dong.

12 And so what I'd like to do is break now until 1:00 and
13 pick up with Hai Wang, I take it.

14 MR. SLATER: Right. I believe that's the last one we
15 have for you today.

16 MS. ROSE: I just wanted to make clear so we might be
17 able to save ourselves some time. In our discussions with
18 plaintiffs on Hai Wang, there's been sort of some uncertainty
19 whether he's going to be called live or via video because he is
20 in New Jersey. And if he's going to be called live, I don't
21 think we need to spend time on this --

22 MR. SLATER: He's going to be played by video.

23 MS. ROSE: Okay. There had not been confirmation that
24 he would be played by video.

25 SPECIAL MASTER VANASKIE: Okay. Yes. So we'll go

1 over the designations then starting at 1:00. All right?

2 MR. SLATER: Thank you, Your Honor. Have a good
3 lunch. See everyone back.

4 SPECIAL MASTER VANASKIE: Thanks. See you at 1:00.

5 (Luncheon recess taken from 11:41 a.m. to 1:03 p.m.)

6 SPECIAL MASTER VANASKIE: All right. Thank you.

7 Thanks for accommodating that break. Let's resume.

8 We're going to pick up with Hai Wang. And I have his
9 first excerpt at issue at line 7 of page 90 of his transcript.

10 MS. ROSE: Your Honor, during the break I had an
11 opportunity to go back through these designations with Your
12 Honor's rulings from this morning in mind, and ZHP can drop the
13 objections to page 90, line 7 through 11 and the designation at
14 page 90, lines 14 through 16.

15 SPECIAL MASTER VANASKIE: Okay. Good. So does that
16 take us now to page 118, line 19?

17 MS. ROSE: Yes, Your Honor.

18 MR. SLATER: I will -- if it helps move things along,
19 if counsel's dropping their objection, we'll agree to their
20 counters. I think it's all repetitive and duplicative of
21 what's already there. But if defense wants to put those
22 counters in, I'm not going to argue it.

23 SPECIAL MASTER VANASKIE: Well, the counters at
24 page 118, 119, 120, and 121 will come in?

25 MR. SLATER: If the defense drops their objection,

1 I'll agree to the counters and they can come in.

2 SPECIAL MASTER VANASKIE: I thought it was suggested
3 only as to the counter?

4 MR. SLATER: Oh, maybe it was.

5 SPECIAL MASTER VANASKIE: All right. So are we all
6 good then?

7 MR. SLATER: Yes. I apologize. I was looking at a
8 prior spreadsheet before the final negotiation -- sorry.

9 SPECIAL MASTER VANASKIE: Okay. So are we going to
10 page 226 now?

11 MR. SLATER: Yes.

12 MS. ROSE: Yes, Your Honor.

13 SPECIAL MASTER VANASKIE: And I guess the whole area
14 at issue starts at page 225, line 20?

15 MS. ROSE: Yes, Your Honor.

16 SPECIAL MASTER VANASKIE: All right. Adam, you're
17 seeking to introduce testimony as to why it took time to send
18 out notice?

19 MR. SLATER: Yes, correct, Your Honor. And if you go
20 on page 225, a little bit earlier than where you had
21 pinpointed, at 225, 6 through 18, it establishes the June 19th
22 date.

23 SPECIAL MASTER VANASKIE: Right.

24 MR. SLATER: That the manufacturer stopped selling,
25 and I just asked why there was that delay. He's designated on

1 these topics. And he's the vice president of all of the U.S.
2 entities. And he essentially says he doesn't know, but that
3 doesn't mean I can't ask the question and establish that it
4 happened and ask him if he has an explanation.

5 And he says ultimately on page 227, line 6 to 7, he
6 ultimately says, "it's not my line, duty or responsibility. I
7 don't know."

8 SPECIAL MASTER VANASKIE: Right.

9 MR. SLATER: So to me there's nothing -- I mean, this
10 is directly within his designation of what happened. And my
11 objection to the counter is that he gives all sorts of
12 speculation about what may or may not have happened, but he
13 also confirms even in that line that he doesn't know.

14 So if he doesn't know, I don't think the jury really
15 needs to hear him speculating out loud of things that may have
16 happened when he has no idea if that's what actually occurred.
17 So I think the testimony that we designated should be in and
18 the counter should not be in.

19 SPECIAL MASTER VANASKIE: All right. Nina?

20 MS. ROSE: Thanks, Your Honor.

21 So this line of questioning, the same question is
22 asked multiple times. And the first time it's answered, the
23 full answer is given, which is that he notes that he's not the
24 person in the line of duty for quality assurance or quality
25 control. But "based on my professional experience" -- and

1 that's what he's being asked by counsel and counsel just said
2 they can ask him in his role as a 30(b)(6) witness -- based on
3 his professional experience, he says: You need a time to
4 confirm that, indeed, that the NDMA present in the product
5 using a validated, analytical method, with that the reference
6 standard, you cannot just say, have a speculation over
7 something in the product and report it, it had to be
8 confirmed.

9 So that's the answer. He was asked why it took so
10 long, he gives the answer. And if Mr. Slater is allowed to ask
11 the question, then the witness has to be allowed to answer.

12 And Mr. Slater has gone on to designate when he asked
13 the same question again, a summary, "it's not my line, duty, or
14 responsibility, I don't know," but he's just summarizing what
15 he said before, which is that that's not his area, but based on
16 his professional experience, which is what he's being asked
17 about by counsel, he gives this answer explaining why it took
18 the amount of time that it took.

19 SPECIAL MASTER VANASKIE: Yes, I'll allow the counter
20 to come in. Both the testimony designated by plaintiff and the
21 counter designated by ZHP will come in.

22 MR. SLATER: Got it.

23 SPECIAL MASTER VANASKIE: That takes us now I think to
24 page 283.

25 MS. ROSE: Yes, Your Honor.

1 SPECIAL MASTER VANASKIE: And that also encompasses --
2 the counter starts on page 281 at line 23.

3 MR. SLATER: Let me just look. I thought -- I'm not
4 going to object to their counter. If they want to play that
5 counter, they're welcome to.

6 SPECIAL MASTER VANASKIE: All right. And so correct
7 me if I'm wrong, coming in will be 283, lines 14 to 19; and
8 281, lines 23 to 24.

9 MR. SLATER: Through 282, line 4, Judge.

10 SPECIAL MASTER VANASKIE: Through 282, line 4. I am
11 sorry. You're right.

12 MR. SLATER: That's agreed. That's correct.

13 SPECIAL MASTER VANASKIE: Okay. Now I'm going to 297.

14 MR. SLATER: I thought we worked this out. I guess we
15 weren't able to work it out.

16 SPECIAL MASTER VANASKIE: The question at lines 21 to
17 23 of page 297: And you understand why a patient would be
18 concerned after learning about the NDMA issue, right?

19 And the answer on page 298, lines 2 to 3: Of course I
20 do. I would be concerned too.

21 And you're objecting to this testimony, Nina?

22 MS. ROSE: Yes, Your Honor. I believe that the
23 testimony that we're objecting to starts on page 295. I'm not
24 seeing the row in this chart, so I'm concerned something is
25 wrong.

1 Because this whole line of testimony relates to a
2 consumer email that was sent to the company, and we object to
3 the entire line of questioning on the grounds that a consumer
4 complaint to the company not at issue in the TPP trial is
5 irrelevant and not admissible and barred under motions in
6 limine rulings.

7 MR. SLATER: But what we did was I think -- we had
8 told you, I think, that we dropped 295, 13 to 20; 296, 4 to 16;
9 and 297, 13 to 15 and 18 to 19. And then picked up and left in
10 297 and going forward through 299.

11 So we asked the questions more generally and took out
12 the customer complaint and asked the questions because they go
13 to economic value about -- that's what we've been arguing in
14 court for a few months now. If somebody wouldn't buy it, there
15 would be no value.

16 So we focused on that part and took out the specific
17 language of the customer complaint and just went with the
18 straightforward question.

19 MS. ROSE: So, Your Honor, I believe that's why the
20 295 and 296 designations are not on this chart, but I'm raising
21 it because this whole line of questioning begins with a
22 consumer email and it has to do with patients and concerns
23 about learning about NDMA and individual understandings of what
24 patients believed. Again, we don't think any of that is
25 relevant. This all comes from a patient email.

1 And even if they cut out the patient email, they're
2 asking questions about individual users being concerned about
3 risk of NDMA, which isn't at issue in this trial. And again,
4 we believe all of this raises issues of general causation
5 because if you're getting into patients and health risks to
6 patients, that implicates the defendants' ability to respond to
7 that regarding the actual risk to patients, if any.

8 SPECIAL MASTER VANASKIE: I think this goes to the
9 economic value of the valsartan and overrule the objection.
10 We'll allow that designation from 297, line 21 to line 23; and
11 298, lines 2 and 3.

12 MR. SLATER: And I think that also includes the
13 objections on 299, but I'll double check that, Judge. I think
14 it's all the same.

15 SPECIAL MASTER VANASKIE: I'm going there now.

16 MR. SLATER: Yes, it's all the same, part of the same
17 line of questioning through 299, line 21.

18 SPECIAL MASTER VANASKIE: For the same reasons, I will
19 allow that. I think it goes to what value does the valsartan
20 have, contaminated valsartan.

21 I think the same thing applies with respect to the
22 testimony -- the transcript designated at page 300, lines 23 to
23 301, line 3; and 301, lines 6 to 9. So to the extent there's
24 an objection, it's overruled.

25 MR. SLATER: And just for the record, Judge, then the

1 answer, the final answer is 11 to -- question and answer of
2 that line is 11 to 13 on page 301. It's the same questioning,
3 though. Just so that the record is --

4 SPECIAL MASTER VANASKIE: Is that designated?

5 MR. SLATER: Yeah, that was designated as part of the
6 objection.

7 SPECIAL MASTER VANASKIE: I see, that was designated.
8 I missed it. And that should come in.

9 MR. SLATER: No problem. Thank you.

10 SPECIAL MASTER VANASKIE: Now I think we're on
11 page 500.

12 MR. SLATER: We're moving through this, Judge. You
13 should open a side business, designations-r-us, and you can
14 just do this for people. Nina and I and the others will come
15 in, we can stand in for people and argue these. We all enjoy
16 it so much.

17 (Laughter.)

18 SPECIAL MASTER VANASKIE: I meant what I said on
19 Friday, that -- I think it was Friday -- that these have been
20 well argued.

21 MR. SLATER: I think honestly the --

22 (Simultaneous speakers.)

23 SPECIAL MASTER VANASKIE: Both sides have reasonable
24 positions.

25 All right. I think we're up to page 500, lines 5 to

1 14. And that picks up, I guess, page 502 -- that's what I was
2 trying to figure out here. I have a bunch of question marks in
3 the chart at this point.

4 MS. ROSE: So, Your Honor, maybe I can answer your
5 question. So all this testimony goes to the issue of the IQVIA
6 data, which is at issue in Dr. Conti's expert opinions with
7 respect to damages. And there's a question right now, the
8 Court hasn't ruled on Dr. Conti and the admissibility of
9 Dr. Conti's opinions and particularly with respect to IQVIA
10 data.

11 So our position, really this is flagging it, that if
12 Dr. Conti's opinions related to IQVIA data are disallowed, then
13 all of this would be irrelevant.

14 SPECIAL MASTER VANASKIE: And if it's allowed, it's
15 all relevant?

16 MS. ROSE: Well, we have an objection as well on the
17 grounds that IQVIA data being used for business purposes is
18 different from IQVIA data being used for the expert purposes of
19 calculating damages in a class action trial.

20 I believe that issue came up in another -- we now have
21 gone through so many witnesses. I think that came up in
22 another witness testimony.

23 Adam, if you have a different recollection...

24 MR. SLATER: I think the other witness who talked
25 about it was Jie Wang. I don't think anything was excluded.

1 MS. ROSE: I think that's why we have that we were
2 preserving the objection. It was my understanding that IQVIA
3 data had come in controlling for the Court's ruling with
4 respect to Dr. Conti, so I was preserving our objection on
5 relevance, understanding that I believe Your Honor has already
6 ruled on it.

7 SPECIAL MASTER VANASKIE: All right. So this all
8 comes in if Judge Bumb rules on Conti's testimony?

9 MR. SLATER: It sounds that, yes. I agree that if the
10 Judge says we can't rely on IQVIA data at all and no one's
11 going to talk about it, then this would not come in. But if it
12 comes in, then we think it's relevant and I don't think there's
13 an objection to that anymore.

14 MS. ROSE: Just to clarify, there is an objection, we
15 understand it's already been ruled on. So we're preserving our
16 objection and noting that it would be subject to Judge Bumb's
17 ruling.

18 SPECIAL MASTER VANASKIE: All right. That's fine.
19 What's up next? Is it 541?

20 MS. ROSE: Yes, Your Honor.

21 SPECIAL MASTER VANASKIE: All right. This is your
22 objection, I think, Nina.

23 MS. ROSE: Yes, Your Honor. This would apply really
24 to all of the objections to the testimony starting at 541 and
25 then going through, I believe, 547, line 10. It's a discussion

1 of emails in 2017 discussing making business decisions with
2 respect to valsartan and the valsartan price.

3 We think this is prejudicial and confusing because the
4 manufacturing changes that were at issue took place in 2010
5 through 2013 time frame, and so business decisions with respect
6 to the price or lowering the price of valsartan years later in
7 2017 are irrelevant and confusing because this is long after
8 any changes were made to the product.

9 SPECIAL MASTER VANASKIE: Adam?

10 MR. SLATER: Thank you, Judge. This testimony is
11 actually highly relevant for multiple reasons.

12 One, it establishes the very central and unique role
13 that Baohua Chen played in setting pricing in the United States
14 and it's actually clear -- he actually talks about the fact
15 that Baohua Chen has more intelligence on the API markets, and
16 that's at 543, line 13 to 20, than anybody else.

17 So this whole line of questioning was how Baohua Chen
18 was communicating with the U.S. subsidiaries about price issues
19 and about the fact that they needed to control price so they
20 could maintain market share. That's number one.

21 Number two, the current good manufacturing practices
22 guidelines require that the risk assessment and all steps take
23 place for the entire life cycle of the drug being on the
24 market. It's not something that you do on day one and if you
25 pass you then turn around and don't do it anymore. Everyone

1 agrees this is an ongoing issue, you always have to be
2 evaluating. That's why we have the unknown peaks issues going
3 on for years where they're not following through on these
4 complaints and not telling their customers, yeah, we figured
5 out what this is and this is what it is. So that's another
6 reason.

7 Next, this is dated June 9, 2017, and they're talking
8 about price pressure from Sam's Club, they lost valsartan
9 business at Sam's Club, et cetera, and they wanted to try to
10 avoid losing more market share. This is literally within a
11 month of the email where, our view of the case is, they knew
12 that there was NDMA in the valsartan and didn't tell anybody
13 because they wanted to maintain their market share and keep
14 selling the cheap drugs.

15 So for all those reasons, this is actually central to
16 multiple issues in the case.

17 SPECIAL MASTER VANASKIE: Anything else, Nina?

18 MS. ROSE: Well, I think I would just address the fact
19 when Mr. Slater was talking about the obligation to satisfy
20 current good manufacturing practices throughout the life span
21 of the drug. That's not what this is about. This isn't
22 discussing knowledge, it has nothing to do with nitrosamines,
23 it has nothing to do with it. It's talking about business
24 decisions related to the price of valsartan and it has nothing
25 to do with CGMP. This is talking about business decisions made

1 with respect to price and that's not relevant to the
2 allegations here.

3 SPECIAL MASTER VANASKIE: Yes, I think it is relevant.
4 I'll overrule the objection to this line of questioning.

5 We go to page 605 now?

6 MS. ROSE: Yes, Your Honor. I believe that's the last
7 designation for this witness.

8 MR. SLATER: I'm looking again, Your Honor, at what
9 their counter is to see if we have any room to move on that.
10 But I'm going to look because I had some serious concerns about
11 it when we looked at it originally but...

12 SPECIAL MASTER VANASKIE: Yes.

13 MR. SLATER: Yeah, I can't agree to the 606, 4 to 11
14 and 14, to 607-4. I'm not going to be able to drop my
15 objection to that.

16 I'll argue it when you want me to, but I can't drop
17 that objection.

18 SPECIAL MASTER VANASKIE: Let me read the answer on
19 page 606.

20 All right. Go ahead, Adam, you can argue.

21 MR. SLATER: Thank you, Judge. The question that was
22 asked on -- actually, it was asked on 604 and then was answered
23 on 605, I think we should look at it because I think it covers
24 it --

25 SPECIAL MASTER VANASKIE: Yes --

1 MR. SLATER: -- why this is not needed.

2 If you look at 603, line 10 to 15, he was asked -- and
3 they're talking about the change notification to all of their
4 customers, which Prinston, as a customer of ZHP technically,
5 received the same change notification and was, thus, relying on
6 it just like Teva, Torrent, and any other customer would.

7 And I asked him: Where it says there was no adverse
8 change to the impurity profile -- because that's what it said
9 in the change notification back when the change to the zinc
10 chloride process occurred -- I say -- I ask him on line 12 of
11 603: You learned in June of 2018 that that was wrong. You
12 learned, in fact, that this process change resulted in the
13 creation of NDMA, correct?

14 The answer is designated after a bunch of colloquy on
15 page 605, line 4. He says: I'm here to answer the questions
16 on this particular change notification and this is the one
17 objected before the change is being implemented. The goal is
18 to have no adverse changes in quantitative and qualitative on
19 the impurity profile, and that's what they set out to do,
20 they're going to study the changes.

21 Unfortunately, that was the closest thing to a
22 responsive answer I could get out of this witness at the time,
23 but that's it.

24 He then is asked again on page 606, because I had
25 moved to strike -- this is before Your Honor ruled don't move

1 to strike anymore because this was one of the first depositions
2 we took.

3 And I asked him the same question again and asked:
4 Can you agree to the simple statement that it yielded an
5 adverse change to the impurity profile, meaning NDMA was
6 created?

7 Just focusing on that one phrase in the change
8 notification that ZHP sent to Princeton.

9 And then he gives this long explanation about the
10 change was evaluated, the results are submitted to the FDA with
11 approval, no one expected NDMA. And he keeps saying no one was
12 expecting it, but that's not what I asked. All I wanted him to
13 answer was because the impurity profile actually included NDMA,
14 there actually was an adverse change. So he's not even
15 answering the question there.

16 He didn't really answer it on the first question and
17 answer, but that was much closer to being responsive and didn't
18 inject the, well, the FDA approved it, so -- basically what
19 he's surmising is so why are you blaming us. And I think that
20 that counter is not responsive, it's not necessary to complete
21 the prior testimony and injects what would be very prejudicial
22 concepts, so we ask that the counter be denied.

23 SPECIAL MASTER VANASKIE: All right. Nina?

24 MS. ROSE: Thank you, Your Honor.

25 So this is a situation, and you've ruled on this

1 before, where an identical question is asked multiple times and
2 the answer to that question is fleshed out through the
3 witness's answers both times.

4 I'm not going to comment on Mr. Slater's
5 characterization of the witness or his answers, but here the
6 witness in the designation that we've countered with in 606, if
7 you actually look at the end, the witness makes clear -- he's
8 trying to explain that these questions all suggest that the
9 witness was aware or that ZHP was aware that there was an
10 adverse change to the impurity profile and at the time that it
11 was made and didn't -- suggesting that they didn't disclose it.

12 And he's saying: You keep asking me. It seems like I
13 already know that. No one knows that.

14 He's explaining that this -- in the context of these
15 questions, how they've been designated, he's explaining his
16 answer. And I think if they're going to allow in the testimony
17 at 605, lines 4 through 12, which is part of his answer, then
18 the rest of the answer has to come in too as he's fleshing out
19 and exclaiming he's answered the question.

20 MR. SLATER: Judge, can I just clarify one thing?

21 SPECIAL MASTER VANASKIE: Yes, you may.

22 MR. SLATER: Nowhere in these questions do I ask did
23 they know this or not. All it asks is was the information in
24 the change notification inaccurate because there actually was
25 an adverse change to the impurity profile.

1 And I actually said on page 603: You learned in
2 June 2018 that was wrong.

3 So I didn't say they knew it all along, I don't
4 suggest they knew it. I'm just establishing that the
5 information was inaccurate. All this about we never could have
6 known it and all was never asked in the question I designated.

7 SPECIAL MASTER VANASKIE: I'll sustain the objection
8 to the counter-designation on page 606, lines 4 to 11; and 606,
9 lines 14 to page 607, line 4. All right?

10 MR. SLATER: I think that's it.

11 SPECIAL MASTER VANASKIE: I think that concludes that
12 witness.

13 Does that conclude the ZHP witnesses?

14 MS. ROSE: I believe so, Your Honor.

15 MR. SLATER: I believe so.

16 Again, Mike, who's the master of ceremonies over here,
17 I checked with him over the weekend and he thought it was done.
18 So unless one of us is unnecessarily optimistic, I think we are
19 done.

20 Right, Mike?

21 MR. GRIFFITH: Your Honor, you reserved ruling on a
22 Min Li designation.

23 SPECIAL MASTER VANASKIE: Thank you. I was going to
24 ask about loose ends, so there's a loose end.

25 MR. SLATER: And frankly, I don't think that we need

1 to reargue it, Judge. I think it was the first -- Nina,
2 correct me if I'm wrong, I think it was the first designation
3 that Your Honor may have reserved on. I would be fine with
4 Your Honor just letting us know with an email or something if
5 you wanted to. I don't know if Nina wants to argue it again,
6 but I would be fine not arguing it again.

7 I don't even remember what the issue was, but I'm sure
8 we can trust Your Honor on that one.

9 MS. ROSE: I believe that's right.

10 SPECIAL MASTER VANASKIE: I would have to dig it out.

11 MR. SLATER: Yeah, I'm not asking you to do it right
12 now. I'm certainly not suggesting you have to dig it out right
13 now. If you can or want to, certainly we're here. But I'm
14 just letting you know that we're fine from plaintiffs'
15 perspective not rearguing it.

16 SPECIAL MASTER VANASKIE: And how about you, Nina, are
17 you fine with me just going back and looking at it again and
18 ruling or...

19 MS. ROSE: Yes, I think that's fine, Your Honor. I
20 believe that Adam is correct and that it was the first
21 designation on the chart. And I believe Your Honor had an
22 initial ruling that ZHP's counter could come in and then -- I
23 think it was about a counter. I also don't have the chart in
24 front of me. But we had an initial ruling that ZHP's counter
25 could come in, and then Adam made some arguments and then you

1 decided that you were going to look at it again. So I will
2 agree to do that.

3 SPECIAL MASTER VANASKIE: All right. After we
4 conclude here today, I'll take a look at it and give you a
5 prompt ruling.

6 MR. SLATER: Thank you so much. I think that's it,
7 though, Judge.

8 SPECIAL MASTER VANASKIE: Any other loose ends?

9 MS. ROSE: Your Honor, if I could raise a point that's
10 not related to designations?

11 SPECIAL MASTER VANASKIE: Sure.

12 MS. ROSE: It has to do with the briefing on the issue
13 of the admissibility of Jinsheng Lin and Maggie Kong's
14 testimony. Plaintiffs submitted a brief in response to our
15 brief on Friday, and that brief essentially asks the Court to
16 order additional trial sanctions against ZHP in the form of
17 precluding witnesses -- precluding the presentation of evidence
18 at trial based in large part on some of the same arguments made
19 with respect to discovery issues that form the basis of the
20 Court's adverse inference instruction.

21 So we would ask if we could have the ability to
22 respond to that brief, their arguments that weren't in their
23 initial filing, which was only three pages long, before Your
24 Honor looks at that issue.

25 MR. SLATER: Wait a second. I just -- I'm concerned

1 about one thing. This was briefed in the trial briefs. ZHP's
2 counsel asked for the right to file a supplemental brief on it,
3 to which we could respond. That was what was permitted. I
4 think Judge Bumb ruled on that. I think she -- I think it was
5 her. And then referred -- oh, was it Judge -- okay. The
6 issue, we were told ZHP would file -- sorry, a lot of briefs,
7 Judge.

8 ZHP would file the brief, we could respond. I really
9 don't think that the briefing should continue at this point.
10 There's been trial briefs and two more briefs. I think we just
11 need to get to the point where, when Your Honor is ready, to
12 argue it. If -- you know, maybe next week at some point, maybe
13 before -- I don't know what your schedule is. But I don't
14 think we should be filing any more briefs on this issue.

15 MS. ROSE: Your Honor, can I just be heard briefly on
16 this?

17 SPECIAL MASTER VANASKIE: Yes, you may.

18 MS. ROSE: So just to clarify, in the trial briefs
19 which were submitted simultaneously, plaintiffs raised this
20 issue in a three-page section of their trial brief. We did not
21 include it in our trial brief. We did not know what plaintiffs
22 were going to say and we did not include it in our trial brief.
23 That's why we asked for permission for us to respond. We
24 didn't have anything in writing on the record on that issue.

25 And then in response to our brief, plaintiffs filed, I

1 believe it was a 15-page brief -- may have been 13 -- a 15-page
2 brief that expanded on their arguments far beyond what was made
3 in their trial brief submission, which was only three pages,
4 and brings up a whole issue of the sanctions with respect to
5 Mr. Chen, indicating that there should be additional sanctions
6 by precluding ZHP from bringing the author of the email that
7 plaintiffs had made the centerpiece of their case but do not
8 want the jury to hear his testimony about that email.

9 And I think we think it's a very, very important issue
10 in this trial and we'd like the opportunity to be heard.

11 MR. SLATER: Yes, I don't really agree with their
12 characterization of us asking for new sanctions, et cetera, but
13 again, we don't think that any further briefing should be
14 provided.

15 If so, it should be immediate, it should be short, and
16 we should have the right to apply to Your Honor if more
17 arguments get made. It's obviously an important issue to both
18 sides, but I'm looking to get the issue done.

19 SPECIAL MASTER VANASKIE: Yes, so am I. But I will
20 give you the opportunity, Nina, to respond on this question.
21 Limit your response to the request for additional sanctions
22 or -- yes, request for additional sanctions.

23 And by when can you get me that response?

24 MS. ROSE: Would Thursday be okay, Your Honor?

25 SPECIAL MASTER VANASKIE: Thursday would be

1 fine.

2 MS. ROSE: Thank you.

3 MR. SLATER: When do you think you want to hear any
4 argument on this one, Judge?

5 SPECIAL MASTER VANASKIE: Let me look at my calendar.
6 I can do it next Monday, October 7th.

7 MR. SLATER: That works, Your Honor.

8 SPECIAL MASTER VANASKIE: Let me just double check.

9 THE LAW CLERK: And Judge Vanaskie, this is Loretta.

10 SPECIAL MASTER VANASKIE: Yes.

11 THE LAW CLERK: Do you have a time? I'll get together
12 a text order.

13 SPECIAL MASTER VANASKIE: Yes. Let me just double
14 check my --

15 THE LAW CLERK: Sure.

16 SPECIAL MASTER VANASKIE: -- calendar that I'm not
17 double booking myself.

18 And I'm not. Yes, 10:00 a.m. if we could do it.

19 THE LAW CLERK: Sure. Thank you.

20 SPECIAL MASTER VANASKIE: Thanks, Loretta.

21 MS. ROSE: Your Honor?

22 SPECIAL MASTER VANASKIE: Yes.

23 MS. ROSE: Can I check with other members of my team
24 who might be the ones arguing this? I'm not sure -- it might
25 be me, but I'm not positive, so I just want to check with them

1 on their availability once we --

2 SPECIAL MASTER VANASKIE: Yes. We'll tentatively -- a
3 hard deadline for this Thursday for your responsive brief.

4 MS. ROSE: Thank you.

5 SPECIAL MASTER VANASKIE: Tentatively we have oral
6 argument scheduled for Monday, October 7th at 10:00 a.m.

7 MR. SLATER: Great.

8 MS. ROSE: Thank you, Your Honor. I will let you know
9 promptly.

10 SPECIAL MASTER VANASKIE: Nina, you can get back to me
11 as soon as you can.

12 MS. ROSE: I will.

13 SPECIAL MASTER VANASKIE: Anything else for today?

14 MR. SLATER: Not that I'm aware of. But every time
15 you ask it, someone else comes up with something.

16 MR. STANOCH: Here I am, Your Honor. David Stanoch.

17 This has nothing to do with designations, Judge, and
18 it can probably wait. It's in the area of housekeeping.

19 Wholesaler defendants have filed a motion about objections
20 raised during a losartan deposition we took, and I know
21 Mr. Geoppinger is not on now and I'm not trying to argue
22 anything. I'm just -- for scheduling purposes. They filed
23 their motion last week.

24 We often do this by letter brief. Your Honor will
25 remember this from years ago. We argue these things through

1 letter brief. I don't need an answer today, but if we could
2 get some clarity. If you want me and Mr. Geoppinger to get on
3 a call with you to do a schedule, or if you want a letter
4 versus a brief. We'll do whatever you want given that our
5 focus is a hundred percent on these designations, but this
6 little thing came up.

7 I don't mean to belittle it, but this came up, we just
8 want to make sure we do it the right way.

9 (Simultaneous speakers.)

10 MR. STANOCH: It's not for the trial, Judge, it's not
11 for the trial.

12 SPECIAL MASTER VANASKIE: It's not for the trial and
13 so I put it on a back burner.

14 MR. STANOCH: That's fine. We just don't want to have
15 a waiver of us not answering.

16 Again, I'm not arguing because Mr. Geoppinger is not
17 here. We say defer this issue until after the trial and then
18 we can brief and argue it, but I don't want to prejudice
19 Mr. Geoppinger's motion.

20 SPECIAL MASTER VANASKIE: Yes, I don't want to
21 prejudice -- if he feels it needs to be decided more promptly
22 than that, we will get to it, but I did put it on a back burner
23 while we're doing the deposition designations.

24 And perhaps what I'll do is issue an order that
25 requires a response by a date certain and then we can go from

1 there. I take it -- I know I should know the answer to this.
2 But I don't have anything scheduled on losartan, irbesartan at
3 the present time?

4 MR. STANOCH: That's correct.

5 SPECIAL MASTER VANASKIE: All right. Jacob, did you
6 want to be heard?

7 MR. RAE: Yes, Your Honor. So I think on the Torrent
8 deposition designations side of things, we had a few
9 designations for Bernadette Attinger, Dawn Chitty, and Sushil
10 Jaiswal that we had deferred addressing. And Mr. Nigh and I
11 had discussed possibly addressing those today. I'm not sure if
12 we want to go forward with that or I know we have a hearing
13 scheduled for this Thursday where we're also going to be
14 dealing with the last four Torrent witnesses, which Your Honor
15 will be pleased to hear I think there's a relatively small
16 number of both designations and objections in those four
17 depositions, so I think we'll move through those pretty
18 quickly.

19 I don't have a strong view of whether we would clean
20 up last week's lingering issues today versus Thursday. I just
21 wanted to raise that those issues are out there and that we
22 should be doing it either today or on Thursday, I think.

23 SPECIAL MASTER VANASKIE: All right. Daniel, you
24 agree?

25 MR. NIGH: I do. And I don't have a strong preference

1 one way or the other in terms of the timing.

2 SPECIAL MASTER VANASKIE: All right. Well, here's
3 what I'm going to ask counsel to do, and that is to write to me
4 to let me know what exactly has been deferred so we could
5 address it on Thursday -- all right? -- with the other Torrent
6 witnesses.

7 MR. NIGH: Yes, Your Honor.

8 MR. RAE: Yes, Your Honor. And I assume that writing
9 could be informal in an email; is that correct?

10 SPECIAL MASTER VANASKIE: Yes, it can be. Yes,
11 informal by way of email. All right?

12 Is there any other loose ends to address?

13 Do you remember that one day, Adam, I kept asking at
14 the end of the day, anything else, and there's another thing.
15 And you told me never ask that question.

16 (Laughter.)

17 MR. SLATER: I do remember that. I think we added
18 about 40 minutes to the conference.

19 SPECIAL MASTER VANASKIE: Yes. Anything else for
20 today?

21 MR. SLATER: Nothing from plaintiffs, at least this
22 plaintiff.

23 SPECIAL MASTER VANASKIE: Okay. And I'm not hearing
24 anything from the defense or any defendant, so we'll see you
25 again on Thursday. All right?

1 MR. NIGH: Thank you, Your Honor.

2 SPECIAL MASTER VANASKIE: Thank you very much.

3 Bye-bye.

4 (Matter adjourned at 1:45 p.m.)

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8 I certify that the foregoing is a correct transcript
9 from the record of proceedings in the above-entitled matter.

10

11 /S/ Sharon Ricci, RMR, CRR
12 Official Court Reporter

13 September 30, 2024
14 Date

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